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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,039	07/31/2003	Szu-Min Lin	JJM-346CIP1	9647
26285	7590	07/22/2008	EXAMINER	
K&L GATES LLP			JOYNER, KEVIN	
535 SMITHFIELD STREET				
PITTSBURGH, PA 15222			ART UNIT	PAPER NUMBER
			1797	
			MAIL DATE	DELIVERY MODE
			07/22/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/632,039	LIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	KEVIN C. JOYNER	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 13 May 2008.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-18 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-18 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 5/13/08.

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 13, 2008 has been entered.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1 and 3-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Addy et al. (U.S. Patent No. 5,961,921) in view of Ferrel (U.S. Patent No. 5,653,045).

Concerning claims 1, 9, 10 and 15, Addy discloses a method for cleaning and sterilizing a medical device comprising:

Placing the device into a container;

Treating the device in the container with a liquid substance comprising a hydrogen peroxide (concerning claims 6, 7, 13, 14 and 16; column 7, lines 15-30), wherein a predetermined amount of the liquid substance is retained in the container (column 7, lines 1-10; column 7, lines 55-68; column 23, lines 12-26);

Vaporizing the liquid substance in the container to create a sterilant vapor; and

Contacting the device with the vapor to effect sterilization of the device (abstract).

More specifically, Addy discloses that the liquid substance contacts the device and is vaporized to complete sterilization of the device, wherein contacting the device with said substance includes physical placement and condensation or aerosol spray. The physical placement is defined by Addy as placing a reservoir containing the substance in contact with the device (column 7, lines 1-10). As such the substance is retained in the reservoir. Furthermore, applying a spray of the substance to the device would require a certain amount of time in order to contact the entire device. During this process, at least a portion of the substance which has already been sprayed on the device is retained, as retain is defined as holding in place or to continuing to use. Addy does not appear to disclose cleaning the device with a cleaning solution or rinsing the device with a rinse solution comprising hydrogen peroxide (concerning claims 4, 5, 11, 12, 17 and 18). Ferrel discloses a method for cleaning and decontaminating (column 5, lines 40-45) wafer devices or medical devices (although the process is described for a silicon wafer, it is noted column 11, lines 40-43 that the process is suitable for medical devices), comprising cleaning the device with a cleaning solution and rinsing the device with a rinsing solution comprising hydrogen peroxide. The cleaning process is provided

in order to remove organic contamination while the rinsing process is provided to rinse said cleaning solution and remove non-metallic particles (column 3, lines 45-55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to clean the device in the container of Addy with a cleaning solution and rinse the device in the container with a rinsing solution to remove organic contamination and non-metallic particles and subsequently rinse the cleaning solution from said device as exemplified by Ferrell. Regarding claim 3, since the rinse solution of Ferrel is comprised of hydrogen peroxide and the liquid substance of Addy also comprises hydrogen peroxide then it would have been extremely obvious to one of ordinary skill in the art to utilize said liquid substance as a rinse solution as well to rinse the cleaning solution from said device and remove non-metallic particles as exemplified by Ferrel..

Concerning claim 8, Addy continues to disclose a method further comprising introducing the liquid substance as a mist (column 3, line 10 states that the introduction of the liquid substance can happen in a plurality of ways including aerosol spray. As broadly interpreted, an aerosol spray produces a mist.).

4. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Addy et al. (U.S. Patent No. 5,961,921) in view of Ferrel (U.S. Patent No. 5,653,045) as applied to claim 1 above, and further in view of Langford (U.S. Patent No. 5,711,921).

Addy in view of Ferrel is relied upon as set forth in reference to claim 1. Addy in view of Ferrel does not appear to disclose a method according to claim 1 further comprising storing the device in the container in sterile form. Langford discloses a method with an improved apparatus, which can be used, for cleaning and/or sterilizing

devices. The patent further discloses a method comprising storing the device in a container in sterile form (as disclosed in column 6, lines 32-37; the device is an endoscope). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method as shown by Addy in view of Ferrel to include the step of storing the device in the container in sterile form as shown by Langford. This eliminates the need for transporting the sterilized device to a storing compartment thus reducing the chances for the device to become contaminated again.

### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 11/024,118. Although the conflicting claims are not identical, they are not patentably distinct from each other because all of the limitations in the claims of the instant application are met with respect to claims 1-19 of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

7. Applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN C. JOYNER whose telephone number is (571)272-2709. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth L McKane/  
Primary Examiner, Art Unit 1797

KCJ